U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

400 Seventh Street, S.W.
Washington, D.C. 20590

NOV 30 2005

Mr. Charles Atlas
President
Oxytec Medical Corporation
5150 East LaPalma Avenue
Anaheim Hills, CA 92807

Reference No.: 05-0253

Dear Mr. Atlas:

This is in response to your September 26, 2005 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device that your company calls the OxyTec 900.

According to your letter, OxyTec 900 is a device intended to supply oxygen to patients who require supplemental oxygen. The interface with the user is through a standard single-lumen nasal cannula. This device consists of a 9-1/2 pound portable oxygen concentrator. When the device is new, the maximum pressure is controlled in software to 12 psi. As the device ages, or under adverse conditions, the maximum pressure can be adjusted up to 18 psi. The diaphragm compressor is capable of generating a maximum pressure of approximately 21 psi when at full power. The device can be powered by multiple power sources, including AC or DC power, or two lithium ion batteries. When using AC or DC power, the device operates and the batteries are charged. The battery pack consists of two, 14.4 volt lithium ion batteries, and the total equivalent lithium content of the battery pack is 7.92 grams. The lithium ion battery pack has been tested pursuant to the United Nations Manual of Tests and Criteria. The carry case for the device serves as the device's protective cover and is integral to the device. You ask whether this device is regulated as a hazardous material under the HMR.

Based on the information provided, it appears that the OxyTec 900 portable oxygen concentrator is not currently subject to the HMR because: (1) the pressure of the oxygen in the device does not exceed 40.6 psia at 20 °C; (2) the lithium ion battery used to operate the device is excepted from the HMR (§ 173.185(c)(2)); (3) the portable oxygen concentrator contains no other materials subject to the HMR; and (4) the battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective insulation of exposed terminals).

173.115
173.185 (c)(2)
175.10

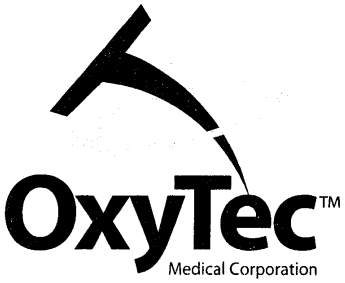
050253

In addition, Federal Aviation Administration (FAA) approval is required before these electronic devices are used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156).

I trust this satisfies your inquiry.

Sincerely,

John A. Gale
Chief, Standards Development
Office of Hazardous Materials Standards



Foster
§ 173.115
§ 173.185
§ 175.10
Applicability
05-0253

September 26, 2005

Ms. Susan Gorsky
U.S. Department of Transportation
Mail Stop THH-10
400 7th Street SW
Washington, D.C. 20590

Re: OxyTec™ 900 Portable Oxygen Concentrator (POC)

Dear Ms. Gorsky:

As a result of recent telephone conversations between John Gale at the DOT and Bob Mogue at OxyTec Medical Corporation we are sending you this letter.

Our goal is to gain approval from the DOT and eventually the FAA for the use of the OxyTec 900 on board aircraft (Reference: July 12, 2005, DOT/FAA 14 CFR Parts 11 and 12, Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft). The OxyTec 900 is similar to the Inogen One approved device.

The OxyTec 900 is scheduled for U.S. home care market introduction in late 2005. It is an FDA 510(k) pre-market notification cleared device. Our 510 (k) number is K043615.

The device can be briefly described as a 9-½ pound portable oxygen concentrator (POC) that includes two lithium ion batteries installed in the device. With the two batteries fully charged the 900 has a duration-of-use of 8 hours at a setting of 2, (which we understand will be a huge benefit to traveling patients compared to the currently approved products). One or two batteries can power the OxyTec 900, and both can be removed for quick replacement with spare/extra batteries should the patient desire. In addition, the device can be powered by use of either an AC or DC power cord. When using AC or DC power, the device operates and the batteries are charged. The carry case also serves as the devices protective cover and is integral to the device.

The device is intended for use by individuals requiring supplemental oxygen, by and on the orders of a prescribing physician. The user will be ambulatory. The interface with the user will be through a standard single-lumen nasal cannula. Typically, most of the users will be diagnosed with chronic obstructive pulmonary disease (COPD).

5150 East La Palma Ave, Suite 203 Anaheim Hills, CA 92807 office: 714-701-9933 fax: 714-701-9311 web: oxytecmedical.com

During discussions with Mr. Gale, he outlined two areas of interest that needed to be addressed in this letter. Those areas were:

- Lithium Ion Equivalent
- System Pressure

We are pleased to provide the following information in regard to these two topics.

Batteries

The lithium ion batteries used in the 900 have received a Declaration of Conformance (see attached document). The declaration of conformance shows the 8 tests that are required in the DOT Test Matrix and the test results (all pass). This certificate was received from our battery manufacturer Inspired Energy, Inc. The lithium ion equivalent for our batteries is 7.92 grams (see attached document). Each battery is 14.4 volts and carries an Inspired Energy part number NL2024.

Pressure

When the device is new, the maximum pressure is controlled in software to 12 p.s.i. maximum pressure. As the device ages, or under adverse conditions, this could be adjusted to as much as 18 p.s.i. The diaphragm compressor, by its nature, is capable of generating a maximum pressure of approximately 20 p.s.i., when at full power and deadheaded (zero flow).

Outlet gas pressure (the connection point of the nasal cannula) is limited first by the product reservoir pressure (12 p.s.i. – 18 p.s.i. maximum as noted above). The delivery valve (0.045" orifice) restricts it, so that the actual pressure at the outlet gas port during flow is approximately 1 p.s.i. – 4 p.s.i.. It would be possible; however, to get full product reservoir pressure (12 – 18 p.s.i. maximum as noted above) in the oxygen cannula if the end of the cannula was occluded.

We look forward to your comments regarding the OxyTec 900 PAOS in these two areas. If I can provide you with further detail, please feel free to give me or Bob a call.

Sincerely,

OxyTec Medical Corporation

Charles Atlas

Charles Atlas
President

cc: L. Robert Mogue, Director
Sales and Marketing

INSPIRED ENERGY
SOLUTIONS FOR PORTABLE POWER

Declaration of Conformance

PRODUCT: Rechargeable Li Ion Battery Pack NL2024A22

Inspired Energy Part Number: NL2024A22

SECTION I - MANUFACTURER INFORMATION

Inspired Energy, Inc.
25440 NW 8th Place, Newberry FL 32669, USA

Telephone: +1 386 462 3676
Date Prepared: November 5st 2004

SECTION II - CONFORMANCE INFORMATION

The listed products have been tested in accordance with the UN document ST/SG/AC.10/11/Rev.3: *"Amendments to the Third Revised Edition of the Recommendations on the Transport of Dangerous Goods, Manual of Tests & Criteria"* and found to comply with the stated criteria

Test #	Description	Date Tested	Test result
T1	Altitude Simulation	May 6 2004	Pass
T2	Thermal Cycling	July 15 2004	Pass
T3	Shock	July 12 2004	Pass
T4	Vibration	July 12 2004	Pass
T5	Short Circuit	August 9 2004	Pass
T6	Impact (Cell-Level test)	July 2nd 2003	Pass
T7	Overcharge	November 1 2004	Pass
T8	Forced Discharge (Cell-level test)	July 2nd 2003	Pass

Signed:

David W. Hellriegel
Product Test Laboratory manager

Shipping, Handling, Storage & Disposal of Your Inspired Energy Lithium Ion Battery

INSPIRED ENERGY™
SOLUTIONS FOR PORTABLE POWER

Shipping

All Inspired Energy, Li Ion battery packs have been tested in accordance with the UN Manual of tests and Criteria part III subsection 38.3 (ST/SG/AC.10/11/Rev.3) - more commonly known as the UN T1-T8 Transportation tests; and have been found to comply with the stated criteria. As a result they can be shipped unrestricted internationally by any means.

A copy of the compliance certificate is available from Inspired Energy upon request, or may be downloaded from our website.

Inspired Energy Lithium Ion batteries are packaged in accordance with the UN requirements for packaging Lithium-Ion batteries. When re-shipping the same guidelines must be followed.

If packed in boxes containing up to 12 battery packs, the box is required to have strong outer packaging with separation to prevent short circuits.

If packed in boxes containing more than 12 battery packs, the packaging must additionally be capable of surviving a 1.2m drop without the contents shorting, and must be less than 30kg. In addition the contents must be identified as being Li Ion batteries (Not Lithium) and the box accompanied by a document identifying the contents as being Lithium Ion batteries (Usually the packing slip)

An example of the label used by Inspired Energy is shown above.

We do not recommend that Li Ion batteries be installed into your device prior to shipping.

End users may carry small quantities of spare battery packs in carry-on luggage without restriction.

You may encounter misunderstanding amongst shipping companies who are not familiar with the differences between Lithium-metal and Lithium-Ion batteries, & may need to assist them by explaining the difference.

Lithium-Ion batteries are not regulated (i.e. they have no transportation restrictions) as long as:

(i) Each individual Li-ion battery pack contains less than 8g of "Equivalent Lithium". This is established by the following calculation:

Number of cells X Cell Capacity X 0.3 = grams of "Equivalent Lithium"

For example, the NL2020A22 battery is calculated as follows: 12 x 2.2 x 0.3 = 7.92g.

(ii) The battery has been tested to the UN/DOT transportation tests (commonly know as the T1-T8 tests). This is demonstrated in the declaration document discussed above.

(iii) They are packaged as detailed above

Inspired Energy, Inc. 25440 NW 8th Place, Newberry. FL 32669
US toll free: 1-888-5-INSPIRE (1-888-546-7747) Tel: 352 472 4855, Fax: 352 472 4859
www.inspired-energy.com

Shipping, Handling, Storage & Disposal of Your Inspired Energy Lithium Ion Battery

INSPIRED ENERGY™
SOLUTIONS FOR PORTABLE POWER

Handling

- Avoid shorting the battery
- Do not immerse the battery in water
- Do not disassemble or deform the battery
- Do not expose to, or dispose of, the battery in fire
- Avoid exposing the battery to excessive physical shock or vibration
- Keep the battery out of the reach of children
- Do not use any battery that has been damaged in any way
- Always charge in accordance with the manufacturer's instructions, using specified chargers only
- Do not use modified chargers

Storage

Inspired Energy Lithium Ion battery packs can be stored from -20°C to +60°C at up to 80% relative humidity. However they are best stored below 21°C in a cool, dry, well-ventilated facility free from corrosive gas or vapor.
Storage at elevated temperatures (Above 45°C) may degrade battery performance and reduce battery life.
Storage at low temperatures may affect initial battery performance

Disposal

All Inspired Energy Lithium Ion batteries are classified by the US federal government as non-hazardous waste and are safe for disposal in the normal municipal waste stream.
These batteries, however, do contain recyclable materials and are accepted for recycling by a number of regional battery recycling programs.
In North America contact the Rechargeable Battery Recycling Corporation (RBRC) at www.rbrc.org
In Europe contact the European Portable Battery Association. (EPBA) www.epbaeurope.org

Inspired Energy, Inc. 25440 NW 8th Place, Newberry. FL 32669
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